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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,623	06/27/2001	George R. Schwartz	41145-1001	6743

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EXAMINER

SCHOPFER, KENNETH G

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 11/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,623

Applicant(s)

SCHWARTZ, GEORGE R. *CS*

Examiner

Kenneth G Schopfer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Reissue Applications

1. The claims presented in this reissue application are not in the proper format. A “clean” copy of all the claims in the application must be submitted pursuant to 37 CFR 1.173 (b) & (d).
2. Claims 6-14 are rejected under 35 U.S.C. 251 as being drawn to a non-elected invention in the original application. A reissue application may not be used to reclaim an invention that was non-elected in the original prosecution. See *In re Orita* 193 USPQ 145. The applicant elected the species of figures 3 and 4 during original prosecution, thus any claims for the invention of the species of figures 1 and 2 are non-elected claims.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims attempt to claim body parts, e.g. “said patient’s oral cavity” and “said brain.” Correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Liebergen (WO 91/05528).

Referring to claims 1-~~2~~, Van Liebergen teaches all of the limitations of these claims. Van Liebergen teaches an apparatus for inducing hypothermia in a patient that is compatible with X-ray procedures (page 2, line 17) and includes:

- a) an endotracheal tube 4 with first and second ends;
- b) a toroidal shaped bladder 1 surrounding the tube at the first end of the tube such that the tube's first end can be inserted into a patient's trachea whereby the bladder contacts the tissues and blood vessels of said patient's oral cavity;
- c) a source of coolant for supplying coolant to the bladder; and
- d) inlet 2 and outlet 3 coolant conducting elements are connected to the toroidal bladder, whereby coolant is circulated through the bladder of the device and can be used to cool the tissue and blood vessels in a patient's oral cavity.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Liebergen (WO 91/05528).

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Referring to claim 3, Van Liebergen teaches all of the limitations of this claim as described above except for the use of a refrigeration means for supplying coolant to the device. Although not specifically stated by Van Liebergen, it would have been obvious to one of ordinary skill in the art at the time of invention that a refrigeration means could have provided a suitable coolant supply to the bladder in order to lower the temperature of tissue and blood vessels in contact with the bladder.

Referring to claims 15 and 16, Van Liebergen teaches all of the limitations of these claims as described above except for a specific teaching for the use of the device to cool tissues proximate blood vessels located at the rear of the patient's oral cavity. The use of the device of Van Liebergen does teach a method of inducing hypothermia in a patient including the steps of:

- a) inserting a coolant contact comprising a toroidal bladder, inlet tube, outlet tube, and endotracheal tube into the oral cavity of a patient; and
- b) flowing coolant through the bladder via the inlet and outlet tubes to cool tissue and blood vessels in contact with the bladder.

Although the device disclosed by Van Liebergen has an intended use in a method for inducing hypothermia throughout the body, it would have been obvious to one of ordinary skill in the art at the time of invention that the device could be inserted such that the bladder is in contact with tissue at the rear of a patient's oral cavity in order to only cool blood flowing to the brain of a patient.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth G Schopfer whose telephone number is 703-305-2649. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703-308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

KS

KS

July 17, 2002



**LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700**